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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,232	02/07/2007	Per Mansson	MANS3014/REF	3755

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,232	MANSSON ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,16 and 25-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,16 and 25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/43774 to Willner, cited in the IDS filed May 22, 2006, in view of U.S. Patent No. 5,047,326 to Pronovost.

i. Independent claims 1, 26 and 30 are obvious

Willner describes a competition immunoassay in which a sample comprising an analyte is contacted with a neutralizing agent, e.g. an antibody, and the mixture then contacted with a piezoelectric crystal with the assayed antigen thereon. *See* page 10, line 10 to page 11, line 7. With this description, Willner teaches an unlabeled antibody that is capable of binding to a target antigen for use in a piezoelectric crystal detection device. Willner, however, does not teach a mixture of at least two different unlabeled antibodies.

Pronovost describes a competitive immunoassay that utilizes a mixture of different antibodies, in order to detect the presence of multiple antigens corresponding to different biological entities. *See* column 4, lines 25-37.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Willner's antibody solution by including a mixture of different antibodies. The skilled artisan would have been motivated to make the modification because Provonost indicates that such a mixture of antibodies can detect multiple antigens. The skilled artisan would recognize that this mixture would therefore allow multiplexed detection (i.e., simultaneous detection of different antigen). Moreover, the skilled artisan would have had a reasonable expectation of success in combining the teachings of Willner and Provonost because it would have taken only routine skill in the

art to immobilize different antigens on the same piezoelectric crystal in order to make use of Brooker's multiple antibodies to perform a multiplex competition immunoassay.

ii. Dependent claims 2-5, 25, 27-29 and 31-32 are obvious

Regarding claim 2, Willner and Provonost describe an antigen-antibody interaction pair. *See supra* rejection of claim 1.

Regarding claim 3, Willner teaches monoclonal antibodies. *See* page 8, line 3.

Regarding claims 4 and 28, Willner and Provonost do not explicitly describe an antibody concentration in the claimed range. Willner does, however, describe a displacement immunoassay method that utilizes a 0.1 mg/ml concentration of antibody. *See* page 29, lines 15-16. It would have been obvious to one of ordinary skill in the art to modify Willner and Provonost's antibody mixture, taught from the perspective of a competitive immunoassay, to limit the concentration of each antibody to between 0.1 and 0.8 mg/ml. Indeed, the skilled artisan would have arrived at the claimed range based on the doctrine of routine optimization. In a case decided by the precursor to the Federal Circuit, the court stated that a claim is not allowable where the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (stating "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.") In *Aller*, the claims were directed to a process taught by the prior art, except for a specific temperature and acid concentration range. *Id*. The court, however, held that the claims

were not patentable since the skilled artisan could have arrived at the claimed ranges through routine optimization.

The facts of *Aller* are relevant here. Similar to that case, Willner and Provonost teach all the limitations of claims 4 and 28, except for the specific concentration range. Willner does, however, teach an antibody concentration within the range, albeit in a different context (displacement versus competition immunoassay). But because the displacement and competition methods are described as alternative embodiments of the same method, the skilled artisan would have found it obvious to conduct routine experimentation to use the concentration described for the displacement assay and apply it to the competition assay.

Regarding claims 5, 27 and 32, Willner describes antibodies diluted in PBS. *See* page 21, line 8.

Regarding claims 25 and 31, Willner teaches DNT and TNT explosives. *See* page 5, line 8.

Regarding claim 29, Willner describes a probe solution that contains antibody at a fixed concentration. *See* page 32, lines 20-21.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willner and Provonost as applied to claim 1 above, and further in view of U.S. Patent No. 4,375,414 to Strahilevitz.

Willner and Provonost, described above, do not teach a narcotic analyte.

Strahilevitz describes an antibody directed to heroin, in order to detect the drug in a biological material. *See* abstract; column 1, lines 13-15.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Willner and Provonost's antibody mixture to include an antibody to heroin. This modification would allow a user to detect heroin in a biological material, thereby providing a reason for the skilled artisan to perform the modification. Moreover, because the modification simply substitutes one antibody for another in a method that can be applied generally to an antibody, the skilled artisan would have had a reasonable expectation of success.

Claims 16 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner in view of Provonost as applied to claim 1 above, and further in view of U.S. Patent No. 5,420,016 to Boguslaski *et al.* ("Boguslaski").

i. Claim 16 is obvious

Willner and Provonost, described above, do not teach packaging the mixture into a kit.

Boguslaski teaches that assembling various assay system components into a test kit facilitates a convenient and facile use of the components in the assay system. *See* column 7, lines 8-17.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Willner and Provonost's mixture by placing it in a kit. The skilled artisan would have made the modification because Boguslaski indicates that

packaging components in a kit facilitates a convenient and facile use of the components. Moreover, because placing components in a kit involves mere routine skill in the art, the skilled artisan would have had a reasonable expectation of success.

ii. Claims 33 and 34 are obvious

Regarding claim 33, Willner teaches DNT and TNT explosives, as described above. *See* page 5, line 8.

Regarding claim 34, Provonost describes bottles and test tubes that can be used in conjunction with the competitive immunoassay described. *See* column 5, lines 24-26. It would have been obvious to one of ordinary skill in the art to use one of the bottles and/or test tubes to hold the antibody mixture prior to performing the immunoassay. Indeed, the mixture needs to be placed in such a container and the skilled artisan would recognize that a bottle or test tube would be suitable containers to store the mixture.

Response to Arguments

Applicants traverse the rejection of the pending claims. *See* Response filed June 10, 2010. Specifically, Applicants opine that the claimed analytes are distinct from the “antigens” taught by Provonost. *See* pages 5-6 (arguing that the term "antigens" includes a single target since such a target can include multiple antigen markers, whereas "analytes" is broader and therefore must denote a plurality of targets). With this in mind, Applicants argue that Provonost’s description of a mixture of different antibodies directed to different antigens does not teach the claimed different analytes since the antigens can be directed to the same analyte. *See* pages 6-7. With respect

to Provonost's teaching of "a mixture of different antibodies is directed to several antigens," Applicants brush this teaching aside by arguing that "[t]here is no background given to this sentence nor is there any indication of the possibility of having antibodies directed to different analyte." *See* page 6, 4th full paragraph.

Moreover, Applicants argue that Provonost's description of a mixture of antibodies directed to chlamydial and gonococcal strains is not specific enough to conclude that different analytes are used in the same solution of an assay, but it is "most likely" the case that antibodies are held in different solutions and added separately. *See* page 7, second paragraph. Applicants further suggest that had Provonost's antibodies been in the same solution, they would have been claimed or exemplified in the specification. *See* page 7, third paragraph.

Applicants' arguments have been fully considered, but are not convincing. Applicants' interpretation of the terms "analyte" and "antigens" is inconsistent with the claims and specification. For example, independent claim 1 describes each "affinity molecule" as having an affinity with a particular "analyte." Dependent claim 2 recites different types of molecules that comprise the "affinity molecule" and "analyte," including an "antibody-antigen." Reading claims 1 and 2 together, it is clear that the analyte can be simply an antigen and the two are not distinct as argued by Applicants. Moreover, the specification describes a "solution containing unknown amounts of analytes, i.e. antigens." *See* page 3, line 36. This description, with the term "i.e." meaning "that is," therefore establishes that the antigens <u>are</u> analytes. Accordingly, Provonost's

description of a mixture of antibodies directed to "several antigens" teaches the claimed arrangement of a mixture of antibodies directed to different analytes.

Applicants' assertion that Provonost's description of mixture has no "background" is not convincing. Provonost states in no uncertain terms that a plurality of different antibodies directed to different analytes are provided in "a mixture." The term "a" clearly denotes one single mixture of antibodies. No background information is necessary since this description is not vague, uncertain or otherwise unclear.

Furthermore, Applicants' statement regarding Provonost's description of a mixture of antibodies directed to chlamydial and gonococcal strains is also not convincing. Nothing in Provonost suggests that the antibodies are provided in different solutions and added separately. Once again, Provonost clearly states that a "mixture" of antibodies can be used. *See* column 7, lines 16-17. It is unclear how this term can be interpreted as meaning separate antibodies. Moreover, even assuming *arguendo* that Applicants' argument is true – that this particular section does not teach a mixture of antibodies, Provonost nevertheless teaches a mixture of different antibodies directed to different analytes as discussed above. *See* column 4, lines 25-37.

With the foregoing rationale in mind, the prior art rejections are maintained using the prior art of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Unsu Jung/
Primary Examiner, Art Unit 1641